

**REMARKS****Status of Claims**

Claims 1-18 and 31 are canceled. Claims 19-30 and 32-38 are pending. Claims 36-38 are withdrawn by the Examiner as not reading on the elected invention.

**Restriction Requirement**

The Examiner deems the restriction requirement proper, and makes it final. The Examiner has withdrawn claims 36-38 as not reading on the elected invention. Applicants note the sentence fragment of "Claim 31 is" on page 2 of the Office Action.

Applicants respectfully traverse the restriction requirement for reasons of record. Applicants further point to the third sentence of 35 USC 121, which prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application. Applicants understand the Examiner's position to be that the subject matter of claims 36-38 is patentably distinct from the subject matter of claims 19-25 and 32, and therefore would not be subject to an obviousness-type double-patenting rejection in the event that applicants file a divisional application to the subject matter of claims 36-38.

**Title and Abstract**

The Examiner objects to the Title and Abstract as not descriptive of the invention as now claimed. In response, the Title and Abstract are amended. Support for the amendments can be found in the specification as filed, and in claim 19. No new matter is added. Applicants request withdrawal of the objection.

Information Disclosure Statement

The Examiner states that “Palameta et al was not received”. Applicants respectfully traverse. As evidence that Palameta et al was received, Applicants attach a copy of the return receipt postcard, indicating that the IDS and 69 references were submitted and received, with date stamp by the USPTO. Applicants further note that in the event that the submitted copy was not available to the Examiner, a previously-submitted copy of Palameta was readily available to the Examiner in the parent case 09/386,724 (issued as US 6,800,661), which cites the Palameta reference on its face. If the USPTO has misplaced the copy that was sent on Feb. 18, 2004, Applicants request that the copy from the parent case be considered by the Examiner. Applicants request consideration of the reference, as shown by initialing and returning a copy of the previously submitted Form 1449 from Feb. 18, 2004.

Rejection Under 35 USC 112, 1<sup>st</sup> paragraph- Written Description

Claims 1-25 are rejected under 35 USC 112, 1<sup>st</sup> paragraph. Applicants request clarification as claims 1-18 were cancelled by preliminary amendment. The Examiner states that there “is no description in the specification or guidance for the artisan as to what compounds may form prodrugs of the recited long-chain, straight-chain 2-amino-3-hydroxyalkane compound of claim 19” (page 3).

Applicants respectfully traverse. A patent need not teach, and preferably omits, what is well known in the art. *Spectra-Physics, Inc. V. Coherent, Inc.* (CAFC 1987) 827 F2d 1524, 3 PQ2d 1737. Prodrugs are known in the art of pharmaceutical formulations. One of ordinary skill would be apprised of a prodrug in the context of a long-chain, straight-chain 2-amino-3-hydroxyalkane, or prodrug thereof, and a pharmaceutically acceptable carrier, wherein the

carbon chain in the long-chain; straight-chain 2-amino-3-hydroxyalkane is C<sub>16</sub>-C<sub>24</sub>. For example, the disclosed compounds have both a hydroxy substituent and an amino substituent. One of ordinary skill would recognize that either or both of these groups can be converted to functional groups which are readily lost upon administration to a human, such as by hydrolysis in the acidic conditions of the stomach.

An applicant's disclosure need only reasonably convey to the skilled artisan that as of the filing date of the application relied upon, the applicant had possession of the specific subject matter claimed. *Vas-Cath, Inc. v. Mahurkar* (CAFC 1991), 935 F2d 1555, 19 PQ2d 1111. An "additional drug for combination therapy" is not the point of novelty, rather the point of novelty comes in the context of a pharmaceutical composition comprising a long-chain, straight-chain 2-amino-3-hydroxyalkane, or prodrug thereof, and a pharmaceutically acceptable carrier, wherein the carbon chain in the long-chain, straight-chain 2-amino-3-hydroxyalkane is C<sub>16</sub>-C<sub>24</sub>. As the language of the claims is "comprising" it is already understood that the claims can contain any additional component. Dependent claims 32 and 33 further specify the inclusion of an additional drug.

#### Rejection Under 35 USC 102(b)

Claims 19-21 and 24, and 26-28 are rejected as anticipated by EP 0 381 514. Applicants respectfully traverse. The '514 reference does not disclose long-chain, straight-chain 2-amino-3-hydroxyalkanes according to the instant invention. The compounds disclosed by EP '514 contain double bonds or, in the case of L(-)-threo-sphinganine from Fig. 1, a terminal hydroxy group. Therefore, the compounds disclosed by EP '514 are not within the scope of the instant claims. Further, applicants are unaware of any evidence suggesting that the compounds of EP '514 are

converted *in vivo* into the compounds of the instant invention. The examiner has provided no evidence to suggest that alkenes are prodrugs of alkanes, or that such conversion would selectively occur *in vivo* for the recited compounds. If the examiner has indicated by “official notice” that the terminal hydroxy group of L(-)-threo-sphinganine or the double bonds of the remaining compounds of Fig. 1 of EP ‘514 can be selectively removed *in vivo*, applicants request documentary evidence to support such an assertion. Simply put, applicants do not know of any way in which the human body might be capable of metabolising the compounds of EP ‘514 as prodrugs in order to arrive at the subject matter of the instant claims.

#### Rejection Under 35 USC 103(a)

Claims 22-23, 25, 29-30, and 32-35 are rejected as obvious over EP 0 381 514. Applicants respectfully traverse for reasons as indicated above. The compounds of EP ‘514 are not prodrugs of the instant compounds, and the examiner has provided no evidence to suggest that the terminal hydroxy group of L(-)-threo-sphinganine or the double bonds of the remaining compounds of Fig. 1 of EP ‘514 can be selectively removed *in vivo*. The compounds of EP ‘514 are neither prodrugs nor homologs of the instant compounds. For example, L(-)-threo-sphinganine has a terminal hydroxy group. There is no suggestion in the cited art to remove the terminal hydroxy group while also changing the length of the carbon chain to arrive at the instantly claimed subject matter. Applicants maintain that it would not be obvious to select two such manipulations of the EP ‘514 compounds simultaneously out of the universe of possible chemical modifications. Furthermore, the examiner’s citation of Henze is out of date. The CCPA

later held that the presumption of obviousness for homologs does not extend beyond adjacent members of a homologous series. In re Elpern (CCPA 1964) 326 F2d 762. Therefore, compounds that differ by more than one methylene unit from the compounds cited by the Examiner are not presumed to be obvious according to Henze.

Applicants respectfully request withdrawal of the rejection.

#### Rejection Due to Obviousness-Type Double-Patenting

Claims 26-31 are rejected under obviousness-type double-patenting over claims 1-9 of U.S. 6,800,661. Applicants respectfully traverse on the basis that the instant claims are of differing scope from the claims of the '661 patent, and are therefore not rendered obvious by the claims of the '661 patent.

#### CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

**AUTHORIZATION**


The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4126-4012. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4126-4012. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

Dated: June 15, 2005

By: \_\_\_\_\_

  
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